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TECHNICAL INFORMATION

CHARDACK·GREATBATCH
DEMAND PACEMAKER

128-419.P 35

MODEL 5841

FOR IMPLANTED USE

'69

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Medtronic's Phone Number
has been changed to:
612/781-6061

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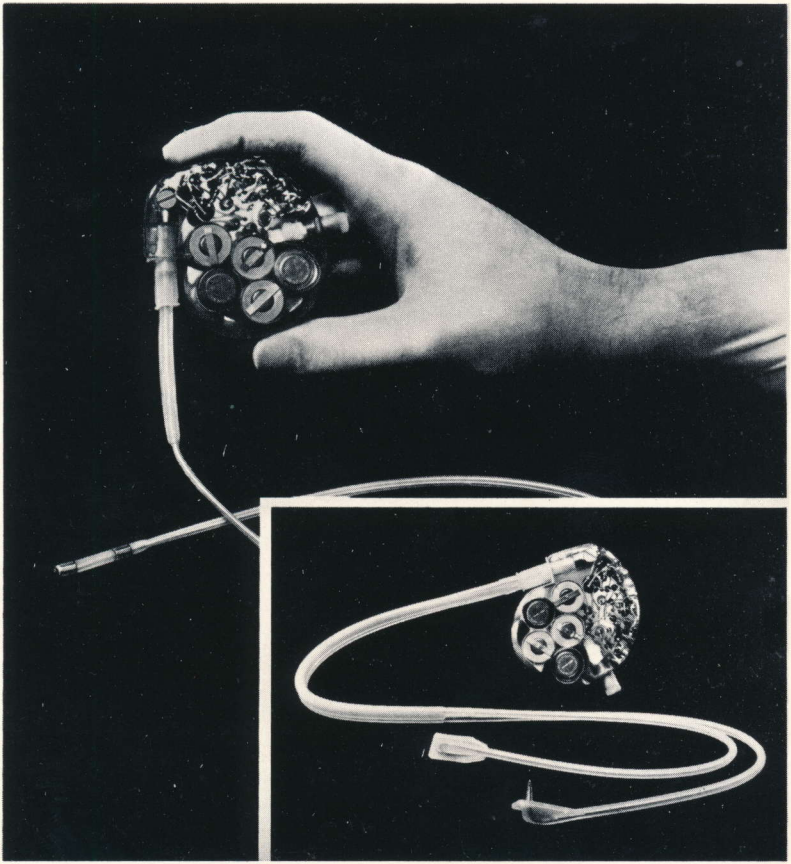

MODEL 5841
CHARDACK·GREATBATCH
IMPLANTABLE DEMAND PACEMAKER

This supplement to the 5870-C Chardack-Greatbatch Implantable Pacemaker instruction manual contains the special information needed to implant the Model 5841 Chardack - Greatbatch Implantable Demand Pacemaker.

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CALIBRATED VERSUS IMPLANTED RATE

The rate calibration as listed on this unit's Quality Control Card (Form 108, located in the pacemaker package) was determined at room temperature (65° F) with a resistive load of 500 ohms. After implantation, the measured free-running rate may be somewhat different because of several interacting factors, such as:

- Body temperature
- Type of electrode
- Polarization phenomenon at interface
- Basic rate of unit

Some of these factors have opposing effects. In general, the observed, implanted rate should compare favorably with the rate on the Quality Control Card. However, in order to secure an accurate base line for future comparison, it is recommended that the free-running rate be recorded on an ECG machine several hours after implantation.

For patients who are in normal sinus rhythm, carotid sinus compression or appropriate drugs may be used to obtain this base line.

(For additional information, see pages 1 and 2 of this manual.)

DESCRIPTION

The Medtronic Model 5841 Chardack-Greatbatch Implantable Pulse Generator operates on the "demand" (or "standby") principle. It is used for patients who are predominantly in sinus rhythm and have only intermittent episodes of symptomatic heart block. It can be used with either endocardiac (Medtronic Model 5816) or myocardial (Medtronic Model 5814) electrodes.

The pulse generator has a sensing circuit which responds to the appearance of a QRS potential at the electrode terminals. This QRS signal is amplified and inhibits the output of the pulse generator for an adjustable period, the duration of which determines the "free-running" rate of the pacemaker. For instance, with the unit set to a "free-running" rate of 60 pulses per minute, any ventricular depolarization (conducted or ectopic) inhibits the output of the pulse generator for one second. If another QRS signal occurs before one second has elapsed, the output is again inhibited for another cycle of one-second duration. If no QRS signal appears in any one-second interval, the pulse generator will fire and will continue to fire at one-second intervals thereafter as long as no QRS potentials appear at the electrode terminals of the system.

The output of the unit appears at the same electrode terminals. The pulse frequency of the unit is adjustable from 50 to 100 pulses per minute. This adjustment may be made before or

after implantation by inserting a surgical skin needle* into the rate control located on the periphery of the pulse generator housing. When the demand pacemaker is connected to the heart, the rate range may be lowered by about 10% (ie, unconnected range: 50-100 pulses per minute, implanted range: 45-90 pulses per minute). This effect is due to the inherent delay between the pacemaker pulse and myocardial activation. The exact amount of reduction in rate is determined by the shape of the R wave elicited by the pacemaker impulse.

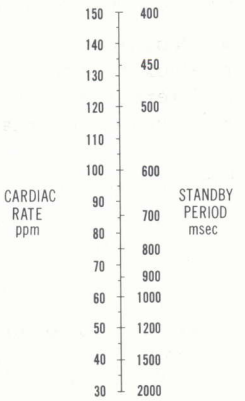

Figure 1. Relationship Between Cardiac Rate and Standby Period

Unlike the standard 5870-C pulse generator, the demand unit has only one control, the rate control. The pulse amplitude is fixed at 11.2 ma (5.6 volts across a 500 ohm load). Pulse amplitude is measured 0.5 msec after the leading edge of a 1.7 msec pulse.

Influence of External Electric Fields

We wish to direct attention to the following observations made on the effects of some external electric fields on the output of the implanted Chardack-Greatbatch Demand Pacemaker (Model 5841).

* Anchor skin needle supplied.

Output and/or rate *were not* altered by:

- Proximity to automobile ignition systems or sparkplugs.
- Proximity to incandescent, fluorescent, or neon lights.
- Internal or external D-C defibrillation shocks.
- X-radiation at diagnostic or therapeutic levels of exposure.

Output and/or rate *were* affected by:

- Electro-surgical units used with either cutting or coagulation currents.
- Radio-frequency diathermy.
- Direct contact across the high voltage portion of ignition systems (sparkplug cap to chassis).
- Some electric razors applied to the skin directly over the implanted pulse generator.

In most of the above situations the pacemaker output was suppressed for the period of application of the external electric field. [Suppression due to interference is detectable (by a return to idioventricular rhythm) only in those patients who are in complete block at the time the interference occurs.] Pacemaker output resumed when the source of interference was withdrawn and no after effects on pulse generator function were observed.

Much of this information was obtained from work done on experimental animals* and the results may not apply to man in every case. In tests run on a patient with the same electric razor cited above, it was impossible to suppress pacemaker output with any placement of the razor. Obviously, susceptibility to some of these electric fields varies from case to case. Nevertheless, these experimental observations should serve to draw attention to some potential sources of interference.

* Unpublished data from Wm. M. Chardack, M.D.

We also wish to emphasize that unipolar electrode systems are more than ten times more susceptible to interference from external electric fields than are bipolar electrode configurations. Although the Model 5841 Demand Pacemaker can be operated with unipolar electrodes, we strongly recommend that bipolar electrodes be used where feasible.

NOTES ON THE OPERATIVE PROCEDURE*

The procedure for installation of the demand system is identical to that used for the standard asynchronous systems (see Model 5870-C manual). For instance, when used with the endocardiac electrode (Model 5816 or 5818), the tip of the electrode is positioned and wedged into the apex of the right ventricle. Stimulation thresholds are then determined separately for the ring and tip terminals. Usually the lowest current threshold values will be found when the tip lead is connected to the negative terminal of the test pulse generator. With the electrode in good contact with the endocardium a threshold current of approximately 1 ma should be the desired goal. Values in excess of 2.5 ma should not be accepted and the electrode should be repositioned. After a satisfactory position of the electrode has been achieved, the terminals of the latter are attached to the pulse generator. The electrode pin having the lower threshold is mated to the negative socket of the pulse generator.

When a bipolar set of myocardial electrodes is used, the same procedure should be followed (see also the manual for Models 5860, 5870). Thresholds should be determined separately between each electrode and an indifferent electrode such as a needle or other instrument in contact with subcutaneous tissue. The electrode terminal which exhibits the lower threshold for stimulation should be connected to the negative terminal of the demand pulse generator.

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*By William M. Chardack, M.D.; 144 Ivyhurst Road; Buffalo, New York 14226.

The demand unit can also be used in patients in whom a bipolar electrode system has been transformed into a unipolar one (caution: see page 4). The input and output of the demand pulse generator will then appear between the single endocardiac or myocardial electrode and an indifferent electrode such as a subcutaneous plate or wire (Medtronic Model 5814-7). In a unipolar system the driving heart electrode should be connected to the negative terminal of the demand pulse generator and the indifferent electrode to the positive terminal.

Checking the Demand Feature

If the patient is in block when the unit is implanted, and his idioventricular rate is below that of the demand pulse generator, the heart rate will be completely determined by the implanted system. It is sometimes possible to check the suppression feature of the demand unit by watching for extrasystoles. These are likely to appear when the electrode is being wedged against the endocardium. Each extrasystole should suppress the output of the pulse generator for a period determined by the rate to which the unit has been set (see Figure 1). This "free-running" rate should be adjusted to be several beats below the patient's P-wave rate at rest.

If the patient is in sinus rhythm at the time of operation, the output of the demand pulse generator will be suppressed as long as the patient's heart rate exceeds that of the implanted unit. Under these circumstances, competence of the implanted standby unit can be demonstrated by slowing the patient's rate with carotid sinus compression or administration of appropriate drug therapy. In some patients these interventions may be ineffective or undesirable.

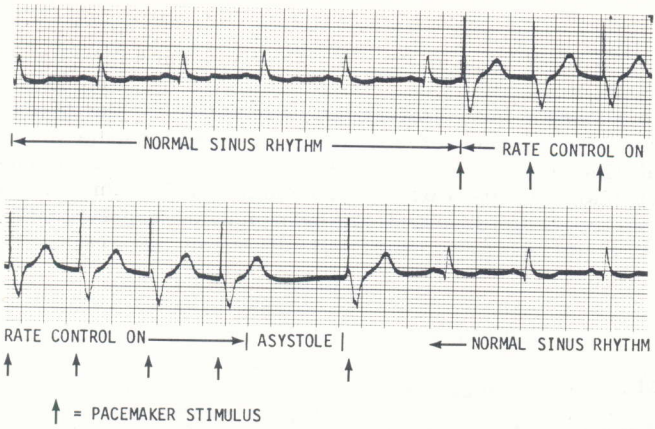

Figure 2. Effect of the External Rate Control on the Implanted Demand System

The external rate control* provides a convenient alternate method of checking the implanted pulse generator. The rate control forces the pacemaker to discharge by transmitting radio-frequency bursts from a coil antenna placed on the skin over the implanted unit. The rate control is set at a rate greater than the patient's sinus rate, forcing the pacemaker to discharge at the higher rate (Figure 2). Pacemaker stimuli, each followed by a ventricular depolarization, appear on the electrocardiogram. Artificial pacing at a high rate depresses the activity of the patient's natural pacemaker (sinus or ectopic), so when the antenna is removed a short asystole results. If the asystole exceeds the standby period of the demand pacemaker, it discharges and induces a ventricular depolarization.

* Medtronic Model 5855, External Rate Control.

A schedule for checking the competence of the implanted demand system must of necessity be determined arbitrarily. During the first two weeks after implantation it should be checked daily. Thereafter, a monthly or bi-monthly check seems to be a reasonable recommendation.

NOTE

We wish to emphasize that multifocal tachy-arrhythmias and other ectopic activity occurring in the postoperative period require immediate and aggressive treatment, notwithstanding the fact that a demand unit has been used. In some instances such arrhythmias can be controlled by drugs alone, but in others an increase in the driving rate is also required.

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SUPPLEMENTAL INFORMATION

Supplemental information may be obtained from your local Medtronic representative, or directly from Medtronic.

Write: Medtronic, Inc.
3055 Old Highway Eight
Minneapolis, Minnesota 55418 USA

Phone: Area 612/781-6855
Consultation is available on a 24-hour basis.

European Service Center:

Schipol Airport East, Building 144
The Netherlands

Phone: 020-157495

Telex: 14498

LIMITATION OF WARRANTY—REPLACEMENT CREDIT AGREEMENT

Please Read Carefully

1. In spite of the care employed in the design of circuitry, the selection of components, the manufacturing process, and the checking and testing prior to acceptance as a finished product, some Chardack-Greatbatch Implantable Cardiac Pulse Generators will fail in the extremely hostile environment of the human body. Therefore, Medtronic, Inc. does not assume any liability for malfunctions from any cause other than to the extent set forth in this Replacement Credit Agreement. Nor does Medtronic, Inc. warrant or guarantee the Chardack-Greatbatch Implantable Cardiac Pulse Generator for any specific length of time.

2. In the event of Chardack-Greatbatch Implantable Cardiac Pulse Generator malfunction due to structural defect, component failure or battery exhaustion within three (3) years of the original date of implantation, a pro-rata credit will be allowed against the purchase price of a new Chardack-Greatbatch Implantable Cardiac Pulse Generator, but only when said purchase is made for replacement in the same person. For each full month of service less than three (3) years, an amount equal to 1/36th of the lower of the original or replacement purchase price (per Medtronic, Inc.'s published U.S.A. price schedule) will be allowed on the replacement Chardack-Greatbatch Implantable Cardiac Pulse Generator; provided, however, that for service of less than twelve (12) months an amount equal to the lower of the original or replacement purchase price (per Medtronic, Inc.'s published U.S.A. price schedule) will be allowed on the replacement Chardack-Greatbatch Implantable Cardiac Pulse Generator.

3. For Chardack-Greatbatch Implantable Cardiac Pulse Generators returned without defect, but otherwise qualifying for replacement credit under paragraph 2 above, one-half (½) of the pro-rata credit stated therein will be allowed.

4. Determination of Chardack-Greatbatch Implantable Cardiac Pulse Generator defect will be made by Medtronic, Inc. at Minneapolis, Minnesota, U.S.A., after inspection of the returned unit. Units returned for consideration of credit allowance shall become the property of the manufacturer.

5. Prompt return of the removed Chardack-Greatbatch Implantable Cardiac Pulse Generator accompanied by complete circumstantial information is of essence for credit determination. Medtronic, Inc. will evaluate and determine the credit allowance, if any, upon receipt of the returned unit and complete circumstantial information.

6. Chardack Heart Electrodes used with the Chardack-Greatbatch Implantable Cardiac Pulse Generator are excluded from this Replacement Agreement because their structure may be damaged by improper handling either before or during insertion. For this reason, Medtronic, Inc. cannot warrant the Chardack Heart Electrode but may elect, at its discretion, to furnish replacement Chardack Heart Electrodes at no charge when this appears justified. Used Chardack Heart Electrodes returned shall become the property of the manufacturer.

The Replacement Credit Agreement herein outlined is in lieu of all warranties, expressed or implied, and all other obligations on its part, and Medtronic, Inc. neither assumes nor authorizes any other person to assume for it, any other liability in connection with the sale or use of the Chardack-Greatbatch Implantable Cardiac Pulse Generator or Chardack Heart Electrodes. There are no warranties which extend beyond the terms hereof.